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10/551,655	07/13/2006	Shinichi Ayabe	8062-1031	8011
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YOUNG & THOMPSON			PAK, YONG D	
209 Madison Street				
Suite 500			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,655	AYABE, SHINICHI	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 January 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) 1-23, 26-31 and 33-50 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 24, 25 and 32 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 28 September 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 9/28/05.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP04/04214.

The amendment filed on January 28, 2008, amending claims 1-6, 10-11, 17-19, 22-28, 32-34, 44, and 47-48, has been entered. The preliminary amendment filed on September 28, 2005, amending claims 3, 13, 17-20, 22-23, 26, 29, 32-36, 40, 43-45 and 47, has been entered. The amendments contain no new matter.

Claims 1-50 are pending. Claims 1-23, 26-31 and 33-50 are withdrawn. Claims 24-25 and 32 are under consideration.

Election/Restrictions

Applicant's election with traverse of Group IV (claims 24-25 and 32) in the reply filed on January 28, 2008 is acknowledged. The traversal is on the ground(s) that since Hamanatsuka neither discloses nor suggests a 2-hydroxyisoflavanone dehydratase of SEQ ID NO:1 or 3, said reference fails to satisfy the art based requirement of PCT Rules 13.1 and 13.2 and the instant invention has unity of invention. This is not found persuasive because not all claims drawn to a 2-hydroxyisoflavanone dehydratase is drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or 3. For example, claim 24 (the elected invention) is drawn to a 2-hydroxyisoflavanone dehydratase comprising amino acids of SEQ ID NO:3. Since the claim does not limit to which specific amino acids of SEQ ID NO:3, the claim is drawn to any polypeptide having 2-hydroxyisoflavanone dehydratase activity that comprises any amino acids, as little as two, of SEQ ID NO:3. Since Hamanatsuka et al. discloses a polypeptide having

2-hdroxyisoflavanone dehydratase activity and at least two amino acids of SEQ ID NO:3, said polypeptide of Hamanatsuka et al. anticipates the technical feature linking the groups. The requirement is still deemed proper and is therefore made FINAL.

Claim for Foreign Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The certified copy has been filed in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 28, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. MPEP 2422.02. See particularly drawing figure 3A.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, page 29, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 32 is objected to because said claim depends from a non-elected claim. However, in order to expedite the prosecution, Examiner has taken into consideration the subject matter of claim 26 in order to examine claim 32. Therefore, claim 32 has been interpreted as "An isolated 2-hydroxyisoflavanone dehydratase, encoded by the polynucleotide comprising: a nucleotide sequence encoding the 2-hydroxyisoflavanone dehydratase according to claim 24; or a nucleotide sequence complementary to the nucleotide sequence". Appropriate correction, incorporating the limitations of the non-elected claim, into claim 32 is requested.

Claim 25 is objected to for the recitation of "catalyzes a dehydration reaction ofto thereby generate daidzein or genistein". The phrase "to thereby generate" causes confusion to the claim and Examiner suggests deleting "to thereby generate".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the phrase “a nucleotide sequence complementary to the nucleotide sequence”. The metes and bounds of the term in the context of the above claims are not clear to the Examiner. Since the claim does not recite a reference nucleotide sequence on which the complementary sequence is based, the claim reads on any nucleotide sequence encoding a polypeptide having 2-hydroxyisoflavanone dehydratase activity. Examiner requests clarification of the phrase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-25 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24-25 and 32 are drawn to (1) a polypeptide comprising amino acids of SEQ ID NO:3, (2) a polypeptide encoded by a nucleotide sequence encoding the polypeptide of (1), and (3) a polypeptide encoded by a nucleotide sequence

complementary to the nucleotide sequence, wherein the polypeptides of (1)-(3) have 2-hydroxyisoflavanone dehydratase activity.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner has broadly interpreted "amino acids of SEQ ID NO:3" of claim 24 to encompass any two amino acids of SEQ ID NO:3, which amounts to no description on the structure of the polypeptide since any polypeptide of unrelated function will comprise of any two amino acids of SEQ ID NO:3. Regarding claim 32, since the claim does not recite a reference nucleotide sequence on which the complementary sequence is based, the claim reads on any nucleotide sequence encoding a polypeptide having 2-hydroxyisoflavanone dehydratase activity. Further, a polynucleotide comprising a nucleotide sequence "complementary" encompasses partial complementary sequences. Therefore, the claims encompass a polypeptide comprising as few as two amino acids of SEQ ID NO:3 or a polypeptide having any structure, wherein said polypeptides have having 2-hydroxyisoflavanone dehydratase activity. Thus, the claims are drawn to a genus of polypeptide having 2-hydroxyisoflavanone dehydratase activity but having any structure.

In *University of California v. Eli Lilly & Co.*, 43 USPQZd 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the

written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The recitation of “2-hydroxyisoflavanone dehydratase” fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The CAFC in UC California v. Eli Lilly, (43 USPQ2d 1398) stated that: “in claims to genetic material, however a generic statement such as ‘vertebrate insulin cDNA’ or ‘mammalian insulin cDNA,’ without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or

recognize the identity of the members of the genus.” Similarly with the claimed genus of “2-hydroxyisoflavanone dehydratase” proteins, the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

The claims are drawn to polypeptides having 2-hydroxyisoflavanone dehydratase activity, but having any structure. The claims encompass mutants, fragments and variants of any or all polypeptides having 2-hydroxyisoflavanone dehydratase activity that are isolated from any or all sources. The specification only describes a polypeptide comprising the amino acid sequence of SEQ ID NO:3 and having 2-hydroxyisoflavanone dehydratase activity. While MPEP 2163 acknowledges that in certain situations “one species adequately supports a genus,” it also acknowledges that “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.” In view of the widely variant species encompassed by the genus, the one example is not enough and does not constitute a representative number of species to describe the whole genus of any or all fragments, variants, recombinant and mutants of SEQ ID NO:3 or any polypeptides having 2-hydroxyisoflavanone dehydratase activity and there is no evidence on the record of the relationship between the structure of the 2-hydroxyisoflavanone dehydratase of SEQ ID NO:3 and the structure of any or all polypeptides having 2-hydroxyisoflavanone dehydratase. Therefore, the specification

fails to describe a representative species of the genus comprising polypeptides having any structure.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 24-25 and 32.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 24-25 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO:3 and having 2-hydroxyisoflavanone dehydratase activity, does not reasonably provide enablement a polypeptide having any structure and/or any function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 24-25 and 32 are drawn to (1) a polypeptide comprising amino acids of SEQ ID NO:3, (2) a polypeptide encoded by a nucleotide sequence encoding the polypeptide of (1), and (3) a polypeptide encoded by a nucleotide sequence complementary to the nucleotide sequence, wherein the polypeptides of (1)-(3) have 2-hydroxyisoflavanone dehydratase activity.

The breadth of the claims.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner has broadly interpreted "amino acids of SEQ ID NO:3" of claim 24 to encompass any two amino acids of SEQ ID NO:3, which amounts to no description on the structure of the polypeptide since any polypeptide of unrelated function will comprise of any two amino acids of SEQ ID NO:3. Regarding claim 32, since the claim does not recite a reference nucleotide sequence on which the complementary sequence is based, the claim reads on any nucleotide sequence encoding a polypeptide having 2-hydroxyisoflavanone dehydratase activity. Further, a polynucleotide comprising a nucleotide sequence "complementary" encompasses partial complementary sequences. Therefore, the claims encompass a polypeptide comprising as few as two amino acids of SEQ ID NO:3 or a polypeptide having any structure, wherein said polypeptides have having 2-hydroxyisoflavanone dehydratase activity. Thus, the claims are drawn to

polypeptides having 2-hydroxyisoflavanone dehydratase activity but having any structure.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides of virtually any structure. In the instant case, the specification enables only for a polypeptide comprising the amino acid sequence of SEQ ID NO:3 and having 2-hydroxyisoflavanone dehydratase activity.

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification.

While enzyme isolation techniques, recombinant and mutagenesis techniques were known in the art at the time of the invention, e.g. hybridization or mutagenesis, and it is routine in the art to screen for variants comprising multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within the encoded protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Furthermore, while the skilled artisan can produce variants of the polypeptide of SEQ ID NO:3 having the recited structural characteristics using well-known and widely used techniques in the art, the amount of experimentation required is not routine due to the fact that the number of species encompassed by the claims is extremely large.

Therefore, in the absence of: (a) rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function, (b) a correlation between structure and 2-hydroxyisoflavanone dehydratase activity, the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. One of skill in the art would have to test these infinite possible polynucleotides/polypeptides to determine (1) which ones have 2-hydroxyisoflavanone dehydratase activity or which polypeptides have 2-hydroxyisoflavanone dehydratase activity, (2) the specific substrates targeted by such proteins and (3) how to use those polypeptides encompasses by the claims which do not have 2-hydroxyisoflavanone dehydratase activity. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance which respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims.

The state of prior art, the relative skill of those in the art, and predictability or unpredictability of the art.

Since the amino acid sequence of the protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant

of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. In the instant case, neither the specification or the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any polypeptides having the same biological function as that of the polypeptide of SEQ ID NO:3 or predict the function of a polypeptide from its primary structure. In addition, the art does not provide any teaching or guidance as to (1) which amino acids within the polypeptides of SEQ ID NO:3 can be modified and which ones are conserved such that one of skill in the art can make the recited polypeptides having the same biological activity as that of the polypeptide of SEQ ID NO:3, (2) which segments of the polypeptide of SEQ ID NO:3 are essential for activity, and (3) the general tolerance of 2-hydroxyisoflavanone dehydratase proteins to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991 – form PTO-892) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by experiments where single mutations are made

reveal how little is known about the rules of protein stability, and (3) the difficulties in designing de novo stable proteins with specific functions.

The amount of direction or guidance presented and the existence of working examples.

The specification discloses only a polypeptide comprising the amino acid sequence of SEQ ID NO:3 and having 2-hydroxyisoflavanone dehydratase activity. However, the speciation fails to provide any information as to (1) specific substrates associated with the polypeptide of SEQ ID NO:3, (2) structural elements required in a polypeptide having 2-hydroxyisoflavanone dehydratase activity, or (3) which are the structural elements in the polypeptide of SEQ ID NO:3 that are essential to display 2-hydroxyisoflavanone dehydratase activity. No correlation between structure and function of having 2-hydroxyisoflavanone dehydratase activity has been presented. There is no information or guidance as to which amino acid residues in the polypeptides of SEQ ID NO:3 can be modified and which ones are to be conserved to create a polypeptide displaying the same activity as that of the polypeptides of SEQ ID NO:3.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability of the prior art in regard to structural changes and their effect on function and the lack of knowledge about a correlation between structure and function, an undue experimentation would be necessary one having ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of

enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics recited in the claim is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-25 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamanatsuka et al.

Claims 24-25 and 32 are drawn to **(1)** a polypeptide comprising amino acids of SEQ ID NO:3, **(2)** a polypeptide encoded by a nucleotide sequence encoding the polypeptide of **(1)**, and **(3)** a polypeptide encoded by a nucleotide sequence complementary to the nucleotide sequence, wherein the polypeptides of **(1)-(3)** have 2-hydroxyisoflavanone dehydratase activity.

The breadth of the claims.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner

has broadly interpreted “amino acids of SEQ ID NO:3” of claim 24 to encompass any two amino acids of SEQ ID NO:3, which amounts to no description on the structure of the polypeptide since any polypeptide of unrelated function will comprise of any two amino acids of SEQ ID NO:3. Regarding claim 32, since the claim does not recite a reference nucleotide sequence on which the complementary sequence is based, the claim reads on any nucleotide sequence encoding a polypeptide having 2-hydroxyisoflavanone dehydratase activity.

Hamanatsu et al. (Phytochemistry (1998) – form PTO-1449) discloses a polypeptide having 2-hydroxyisoflavanone dehydratase activity (abstract). Regarding claim 24, said polypeptide of Hamanatsu et al. comprises any two amino acids of SEQ ID NO:3. Regarding claim 25, the polypeptide of Hamanatsu et al. catalyzes 2,7,4'-trihydroxyisoflavanone or 2,5,7,4'-tetrahydroxyisoflavanone to daidzein or genistein (page 498-499). Therefore, the reference of Hamanatsu et al. anticipates claims 24-25 and 32.

Other Relevant Art

Akashi et al. (Plant Physiol. 2005 Mar;137(3):882-91. Epub 2005 Feb 25 – form PTO-892) discloses a polypeptide having 2-hydroxyisoflavanone dehydratase activity which is 100% identical to the 2-hydroxyisoflavanone dehydratase of SEQ ID NO:3 of the instant invention (abstract) but is not available as prior art because the reference was published or made known to the public after the instant invention was filed.

Conclusion

Claims 24-25 and 32 are rejected.

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652